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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,872	12/04/2000	Tony Wai-Chiu So	A33477 PCT U	5826

20350 7590 10/17/2003

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EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/17/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/673,872

Applicant(s)

WAI-CHIU SO ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Receipt of Request For Continued Examination, Amendment B, and Information

Disclosure received on July 24, 2003 is acknowledged. Claims 1-6 and 8-24 are pending.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-6, 8-9, 12-19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasting et al (5,041,439) by itself or in view of Yu et al (5,156,836) or WO 97/12602.**

Kasting et al teaches a minoxidil acid salt made from an acid such as hydrochloric acid, acetic acid, or lactic acid (col. 6, lines 44-53). Kasting teaches utilizing 0.1-10% of the active. Water (0-90%), isopropanol, isopropyl alcohol, ethanol (0-85%), or mixtures thereof are taught as solvents. Composition XIV contains 12% active, 54%

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1,2 6-hexanetriol, oleyl alcohol, and 30% ethanol (Note composition XIV). Preferred triols are glycerol and 1,2,6 hexanetriol. Kasting teaches the amount of active also depends on factors such as the severity of the condition, the cause of the condition, the specific active used, etc. (col.7, lines 5-15). Kasting teaches several formulations such as shampoo, gel, mousse, etc.

Kasting et al do not exemplify the minoxidil acid salt.

Yu et al teaches a therapeutic composition for hair loss that contains minoxidil (2%), water, ethanol, propylene glycol (16%), and lactic acid (Note example 3). Yu et al teaches the active agent in the range of .01-40% (col.6, lines 51-53). Further, Yu teaches the volume ratio of ethanol: water: propylene glycol to be 40:40:20 (col. 7, lines 1-3). The composition is applied to the scalp to treat hair loss (Note example 3). Yu teaches lactic acid helps dissolve minoxidil.

WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

Although Kasting et al does not exemplify the addition of the organic salt, it is obvious that the acid is added to form the acid salt derivative of the minoxidil from the teachings on column 6, and it is the amount used is effective to allow the active to become more hydrophilic or soluble.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to the teachings of Yu et al or WO and utilize the instant acid derivative. One would be motivated to do so since both references teach that by adding

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salt to minoxidil, it yields a more soluble form of the active. Further, WO teaches this addition to yield a hydrophilic compound, allows for better penetration into the hair follicles.

**Claims 10-11, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasting et al (5,041,439) by itself or in view of Yu et al (5,156,836) or WO 97/12602 in further view of Uchikawa et al (5,156,836).**

As set forth above, Kasting et al teaches a minoxidil acid salt made from an acid such as hydrochloric acid, acetic acid, or lactic acid (col. 6, lines 44-53). Water (0-90%), isopropanol, isopropyl alcohol, ethanol (0-85%), or combinations thereof are taught as solvents. Yu et al and WO teach utilizing organic acids to solubilize minoxidil.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol, isopropanol alcohol, or benzyl alcohol. See column 4.

It would have been obvious at the time the invention was made to look at Uchikawa and substitute ethanol with benzyl alcohol. One would be motivated to do so since Uchikawa teaches the functional equivalency of ethanol, isopropanol and benzyl alcohol in a composition. Further, one would expect similar results since Kasting teaches the use of ethanol or isopropanol in the composition. Therefore, a skilled artisan would expect similar results by utilizing either alcohol in the composition.

***Response to Amendment***

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The Declaration under 37 CFR 1.132 filed July 24, 2003 is insufficient to overcome the rejection of claims based upon Kasting et al as set forth in the last Office action because: The declaration is not comparing the closest prior art. The examiner has made a rejection based on Kasting et al, Yu et al, and Uchikawa et al, however applicant has made a comparison between Di Schiena and instant invention.

***Response to Arguments***

Applicant argues that the prior art does not teach less than 10% of a polyhydric alcohol.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the claims state: at least 5% active, an effective amount of salt, a solvent, and a co-solvent selected from the group consisting of aromatic or polyhydric alcohols; wherein when the co-solvent includes propylene glycol, it is present in an amount of less than approximately 10%. This recitation only limits the percentage when propylene glycol is utilized. Clearly, Kasting et al composition XIV does not contain propylene glycol, it contains 1,2,6 hexanetriol which is not propylene glycol. Therefore, Kasting et al reads on instant claims.

**Claims 1-6, 8-9, 12-19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5183817) in view of in view of Yu et al (5,156,836) or WO 97/12602.**

Bazzano teaches a minoxidil cream containing retinoic acid, minoxidil (.5-5%), ethanol, propylene glycol (5-50%), and distilled water (up to 10%). Formulation example II contains 1% retinoic acid, 10% minoxidil, 4% cetyl alcohol, 4% ethanol, and up to

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100% water. Bazzano teaches the use of pharmaceutically acceptable acid salt. See column 19, lines 1-25. Bazzano discloses that a major problem in influencing hair growth is obtaining good percutaneous absorption of the active compounds. The retinoid compounds cause excellent absorption of the hair follicles. See column 19, lines 35-40. The formulation can contain any pharmaceutically acceptable carrier, additive, or solubilizer.

The reference does not specify the pharmaceutically acceptable salt.

Yu et al teaches a therapeutic composition for hair loss that contains minoxidil (2%), water, ethanol, propylene glycol (16%), and lactic acid (Note example 3). Yu et al teaches the active agent in the range of .01-40% (col.6, lines 51-53). Further, Yu teaches the volume ratio of ethanol: water: propylene glycol to be 40:40:20 (col. 7, lines 1-3). The composition is applied to the scalp to treat hair loss (Note example 3). Yu teaches lactic acid helps dissolve minoxidil.

WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to the teachings of Yu et al or WO and utilize the instant acid derivative. One would be motivated to do so since both references teach that by adding salt to minoxidil, it yields a more soluble form of the active. Further, WO teaches this addition to yield a hydrophilic compound, allows for better penetration into the hair follicles. Further, since Bazzano is concerned with penetration of the composition into

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the hair follicle one would expect an additive effect of increasing penetration of the composition by adding instant salt. Lastly, Yu et al and WO demonstrate that it is known in the art to add a salt to increase solubility of an insoluble active.

**Claims 10-11, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5,183,187) in view of Yu et al (5,156,836) or WO 97/12602 in further view of Uchikawa et al (5,156,836).**

As set forth above, Bazzano teaches a minoxidil cream containing retinoic acid, minoxidil (.5-5%), ethanol, propylene glycol (5-50%), and distilled water (up to 10%). Yu et al and WO teach utilizing organic acids to solubilize minoxidil.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol, isopropanol alcohol, or benzyl alcohol. See column 4.

It would have been obvious at the time the invention was made to look at Uchikawa and substitute ethanol with benzyl alcohol. One would be motivated to do so since Uchikawa teaches the functional equivalency of ethanol, isopropanol and benzyl alcohol in a composition. Therefore, a skilled artisan would expect similar results by utilizing either alcohol in the composition.

**Claims 1-6, 8-9, 12-19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03638 in view of WO 97/12602.**



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WO teaches a hair care composition containing 0.1-7% minoxidil, 0.1-5% cyclodextrin, 0.5-15% of a minoxidil solvent (propylene glycol), 30-50% monoalcohol (ethanol or isopropanol), and water. Note abstract and examples.

WO 97/03638 does not teach the use of lactic or acetic acid or teach the instant formulation.

WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of WO 97/03638 and WO 97/12602 and utilize the instant acids. One would be motivated to do so since WO teaches that organic acids modify minoxidil to yield a hydrophilic active and therefore is more soluble in water and improves penetration into the hair follicle. Therefore, one would be motivated to add an organic acid to increase minoxidil's solubility in water and improve its penetration.

**Claims 10-11, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03638 in view of WO 97/12602 in further view of Uchikawa et al (5,156,836).**

As set forth above, WO teaches a hair care composition containing 0.1-7% minoxidil, 0.1-5% cyclodextrin, 0.5-15% of a minoxidil solvent (propylene glycol), 30-50% monoalcohol (ethanol or isopropanol), and water. Note abstract and examples. WO teaches utilizing organic acids to solubilize minoxidil.

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The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol, isopropanol alcohol, or benzyl alcohol. See column 4.

It would have been obvious at the time the invention was made to look at Uchikawa and substitute ethanol with benzyl alcohol. One would be motivated to do so since Uchikawa teaches the functional equivalency of ethanol, isopropanol and benzyl alcohol in a composition. Therefore, a skilled artisan would expect similar results by utilizing either alcohol in the composition.

### ***Conclusion***

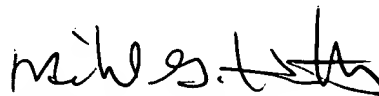
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG



  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER

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